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SENSITIVE
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STATE FOR SEZANEH SEYMOUR IN OES/ENRC

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SUBJECT: INDIA: THE THEORY AND PRACTICE OF ACCESS TO
BIOLOGICAL RESOURCES

REF: SECSTATE 09667

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¶1. (U) SUMMARY: The following answers reftel, paragraph 20 request for information on Government of India (GOI) regulations governing benefit sharing and access to genetic resources. India's National Biodiversity Authority (NBA) is the body responsible for managing and approving access to India's biological resources within a framework of Acts, Rules and Bills that attempt to define requirements for access. In short, the process is inconsistent, implementation is spotty at best, the NBA admits it is a work in progress, and the responsible Ministry doesn't want to talk about it. END SUMMARY

¶2. (U) The National Biodiversity Authority publishes on its website (<http://www.nbaindia.org>) information on regulations and procedures for accessing and claiming intellectual property rights on Indian biological resources. The Embassy also relied on the text of the 2002 National Biodiversity Act and 2008 Biodiversity action plan, and six publications reviewing India's 2002 National Biodiversity Act, its implementation, IPR issues related to biodiversity and traditional knowledge, and the National Biodiversity Strategy and Action Plan published by the NGO Kalpavriksh. This response was informed by discussions with:

- Dr. P. L. Gautam, Chairperson of the NBA.
- Dr. K. Venkatraman, Secretary of the NBA.
- Dr. Arivudai Nambi, Principal Scientist for Biodiversity of the M.S. Swaminathan Research Foundation which provides consultation services for the NBA.
- Dr. Bandyopadhyay, Animal Husbandry Commissioner of the Department of Animal Husbandry and Dairying, Ministry of Agriculture.
- Dr. S. K. Sharma, NBA Committee Member and Director of the National Bureau of Plant Genetic Resources (NBPGR) - the national plant repository.
- Dr. Naresh Kumar, NBA Committee Member and Head of the R&D Planning Division at the Council of Scientific and Industrial Research (CSIR).
- Mr. R. K. Gupta, Head of Intellectual Property Management

Division at CSIR.

-- Dr. B. Ghosh, Deputy Director of the Institute of Genomics and Integrative Biology.

-- Dr. Ravi Chellam, Country Director for the Wildlife Conservation Society.

-- Ms. Krishna Sarma, Managing Partner of Corporate Law Group.

LEGISLATION AND REGULATION OF ACCESS TO BIOLOGICAL RESOURCES

¶3. (U) India ratified the Convention on Biological Diversity (CBD) in 1994. In 2002, it passed the Biological Diversity Act (BDA) and in 2003 published implementation guidance through a set of Rules. In order to manage access to India's biological resources, the Rules established a three tiered structure including the National Biodiversity Authority (NBA), the State Biodiversity Boards (SBB), and the Biodiversity Management Committees (BMC) at the local levels.

¶4. (U) The NBA is designated the sole approving authority for foreign party (including non-resident Indian) access to biological resources in India. It also regulates Indian requests for IPR on biological resources, advises the Central Government on conservation and biodiversity, and is responsible for determining and ensuring equitable sharing of benefits with local populations. It is managed by the Ministry of Environment and Forests (MoEF) and comprised of rotating official members from several GOI ministries and Departments, as well as non-official members from NGOs and universities.

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¶5. (U) The SBBs are responsible for managing resident Indian access to biological resources, and have the power to restrict any activity in their state they determine to be detrimental to biodiversity. However, procedures for obtaining permissions from the SBBs are not well defined, vary from state to state, and different Indian researchers utilize different procedures even within the same state. For example, post has learned that certain Indian researchers merely inform the various SBBs of their activities without making formal access requests.

¶6. (U) The BMCs represent the interests of the local population and document traditional knowledge and resources for IPR-related reference through the People's Biodiversity Registers (PBRs). The NBA and SBBs are supposed to consult them before access or benefit sharing decisions are made regarding use of local resources or traditional knowledge, although this step is often not performed. According to NBA's website, as of September 2008 there were 1453 BMCs nationwide although this number is wildly skewed by the state of Karnataka which reports 1354 BMCs. This is most likely due to Karnataka's comparatively greater proactive interest in protecting its biodiversity.

¶7. (U) The BDA defines biological resources as "plants, animals and micro-organisms or parts thereof, their genetic material and byproducts (excluding value added products) with actual or potential use or value, but does not include human genetic material". According to Ms. Sarma, the definition does not encompass extracts of bacterial and fungal strains. There are four BDA-defined exemptions to the requirement of NBA approval for use:

-- Local people and communities in the area have free access to use biological resources within India.

-- Growers, cultivators, Vaidas, and hakims. (NOTE: Vaidas and hakims are practitioners of traditional medicine, and are not necessarily trained or certified by any authority. END NOTE)

-- Normally traded commodities are exempted from the purview

of the Act via formal notification procedures.

-- Material used for collaborative research through government-sponsored or government-approved institutions subject to overall policy guidelines and approval of the Central Government. (NOTE: This is known as the MOU Exemption. END NOTE)

18. (U) In addition, several additional acts and bills could have an impact on either access to or IPR claims for biological resources. Given that Indian legislation is convoluted and constantly changing, the following may not be an all inclusive list:

-- The Seeds Bill (introduced in 2004 but not yet enacted) would allow farmers, mostly seed producers who intend to engage in commercial sale, to register and license seed varieties.

-- The 2005 Amendment to the Patents Act allows biological products - including living organisms - to be patented, but also permits a patent to be opposed on the grounds that it claims traditional knowledge. A draft technology transfer law currently pending in Parliament may further impact the ability to claim biological resources related IPR.

-- The 2001 Protection of Plant Varieties and Farmers' Rights Act created an Authority which provides a mechanism to register novel finished agricultural products - such as livestock breeds or plant varieties - and gives the registrant exclusive right to produce, sell, market, distribute, import or export the variety. The Authority is not involved in approving access to biological resources in

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India, but may be consulted in determining eligibility for IPR.

-- The Wild Life Protection Act (1972) protects wild animals, birds, and plants in national parks or notified sanctuaries, and creates a permit requirement for research on any biological resource designated under the Act.

-- The Indian Forest Act (1927) and Forest Conservation Act (1980) deal with management of forests, conservation of forest land, and regulation of flora such as bacterial or fungal strains in reserved and protected forests, notified sanctuaries, and national parks.

-- The National Biodiversity Resource Authority is in the process of being created under the Department of Biotechnology; it does not yet exist and a timeline for its establishment has not been fixed. Post was unable to determine what roles or responsibilities it will have in regulating biological resources.

19. (SBU) Actual implementation of the BDA has been troublesome and has created significant confusion among researchers, GOI officials, and even within the NBA itself. Input from our contacts and a Scioff review of available information shows that provisions of the NBA do not appear to be either widely publicized or known. In addition, the procedures are complex and constantly changing, implementation is governed as much by exception as by rule, the decision process is not transparent, and Indian laboratories are looking for ways to avoid, rather than engage, the NBA process.

10. (SBU) NBA's primary mode of information dissemination is their website. However the site is outdated, incomplete, confusing to navigate, and does not provide information on any requirements, beyond NBA approval, necessary for access to biological resources. Dr. Naresh Kumar said that NBA "is still evolving its jurisprudence at every meeting - for every step clarified there are a half step more issues." This is borne out by a quick look at the NBA's 14 expert committees,

of which only three have produced guidelines, four have draft guidelines, and seven have no guidelines. Dr. Bandyopadhyay said that implementation is incomplete and slow. Mr. Gupta said that the NBA is still very unclear about what materials come under its purview and is trying to determine what additional exemptions should exist.

¶11. (SBU) Ravi Chellam noted that NBA had a lack of staff and capacity, which constrained its ability to handle applications in a thorough, timely, and transparent manner. The NBA expert committee and main body has both approved as many as 138 applications in a one day session, raising questions about the thoroughness of the review process and implying that NBA may not adequately confer with technical or traditional knowledge experts before making decisions. While the vast majority of decisions thus far have been in favor of providing access and allowing IPR, without a more defined and transparent process any change in the NBA makeup or increase in influence of anti-sharing NGOs and activist groups could negatively shift future decisions.

¶12. (SBU) Mr. Gupta commented that publishers of scientific journals generally require a researcher to deposit material into an international repository so that other scientists can verify their work. The NBA mandates re-approval for any third-party transfer, which means that the international repository and every individual researcher who wants to access the material for verification would be required to submit an NBA application for access along with the accompanying fee. It is easy to see how this would produce significant delays in research and collaboration and a reluctance to publish findings in legitimate peer-reviewed journals.

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¶13. (SBU) Whether through loose interpretation of the government's collaborative research exemption or through formal treaties or MOUs, our contacts described examples of mechanisms that Indian organizations have established to continue sample sharing and research without NBA involvement. For example:

-- Under the FAO-sponsored International Treaty on Plant Genetic Resources for Food and Agriculture, the germ plasm of crops specifically designated by India can be exchanged, including with non-signatories such as the U.S., without any requirement for NBA approval. The GOI has designated entire repositories under this program.

-- India's Ministries of Agriculture and Health have recently signed an MOU with the U.S. CDC to provide samples of Avian Influenza without requiring NBA approval.

-- Several contacts acknowledged that samples which met the definition of a biological resource continued to be unofficially shared by government, academic and commercial laboratories. One of our contacts works with chemically-produced compounds originally derived from Indian plants. To avoid the NBA process, he has chosen to interpret the NBA's definition to exclude these compounds.

¶14. (SBU) The few SBBs, BMCs, and local communities that are aware of the BDA's provisions appear to be unsure of their role and unaware of their right to negotiate Mutually Agreed Terms (MAT) for use of biological materials. As such, they are often easily cut out of the process by the NBA. A foreign researcher would, in the current process described by NBA, deal only with the NBA or Indian sponsor and not be in contact with any SBBs or BMCs, except in cases where endangered species access permits might be required.

¶15. (SBU) In addition, few states have formed boards and most of those that have lack manpower or technical background to effectively engage on any of the BDA requirements or issues, according to our contacts and the Kalpavriksh publications.

Ravi Chellam said that state boards refer Indian nationals to the NBA for approval to conduct research because they do not want to take a position on allowing or disallowing access.

¶16. (SBU) The composition and roles of BMCs are also a topic of significant public concern and confusion, especially regarding inclusion of appropriate local and tribal group representation for benefit sharing discussions and MAT negotiations. The NBA's website indicates the Indian sponsor is responsible for contacting BMCs to negotiate MAT and benefit sharing on behalf of the foreign party, after which the NBA would approve the arrangement. However, we heard conflicting anecdotes about the actual application of the process which appears to vary considerably depending on state and locality. For example, in Tamil Nadu, NBA officers Dr. P. L. Gautam and Dr. K. Venkatraman said that the process worked as it was supposed to, and Dr. Arivudai Nambi said his organization had liaised with "local authorities." Our contacts in Delhi, however, suggested they dealt only with the NBA and were not aware of any direct discussions or negotiations with the local BMCs.

THE PROCESS FOR REQUESTING ACCESS

¶17. (U) According to the NBA website, foreign parties must file a separate application request for each activity involving biological resources - i.e. for research of material, transfer of material or knowledge, and permission to claim IPR - each of which requires payment of an application fee ranging from INR 500 - INR 10,000 (USD 10 - USD 200). Applications are generally approved within three

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months, and the application process as described is:

-- The foreign party identifies an Indian sponsor institution accredited by the Ministry of Science and Technology that will be responsible for the party's activities in India and also help the foreign party to obtain Prior Informed Consent (PIC) from and negotiate MAT with the relevant BMC or local organization.

-- The foreign party or Indian sponsor then files the application (research, transfer of material or information, or IPR request) with the NBA.

-- The relevant NBA expert committee reviews the application and gives a recommendation to the NBA, which meets at least quarterly to review applications. The expert committee is supposed to consult with relevant technical experts, assess potential impact of the activity, and consult with BMCs to ensure benefit sharing has been adequately addressed.

-- After NBA approves the application and before any activity can begin, the foreign party must sign an agreement with the NBA that specifies the terms and conditions of the activity. Sample agreements are posted on the NBA's website.

-- The NBA dictates constraints for the research activity in the agreements. Clauses might, for example, restrict the quantity or location of the material to be collected, limit time allowed to access the material, require that samples be deposited in an Indian national repository, restrict sharing of the research with any party not named in the agreement absent NBA re-approval, and demand that all research results be shared with Indian institutions.

-- Commercial transfer and IPR agreements may also include these clauses, and will incorporate any discussion of benefit sharing or mutually agreed terms.

¶18. (U) Indian researchers are not required to apply to the NBA to access biological resources within India, although they are supposed to go through the SBBs. However, they do

require NBA approval for transfer of materials or knowledge outside of India (if not covered by an exemption), for transfer for commercial purposes, and for IPR claims.

THE MOU EXEMPTION FAVORS GOVERNMENT INSTITUTIONS

¶19. (SBU) Overall, it appears that the government-affiliated laboratories, including those at universities, find the BDA and NBA to be less restrictive for their international research, largely because they can take advantage of the MOU exemption to share biological resources and knowledge without need for NBA approval. Everyone we spoke with, except the NBA Chairperson and Secretary, openly encouraged us to tell U.S. researchers to use the Ministry-approved-MOU route and to avoid engagement with the NBA for any research-related requests.

¶20. (SBU) Researchers working with private organizations such as NGOs, however, have no choice but to follow the NBA process. Ravi Chellam and others claimed the paperwork requirements and cumbersome process impede their ability to work with international collaborators. Because of the way research in India is organized, these requirements disproportionately impact those organizations working on wildlife and endangered species conservation and with biological resources found in national parks and other protected areas.

LIMITED REQUIREMENTS FOR PERMITS

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¶21. (U) Permits are required for collection of any biological material designated under the Wildlife Protection Act, or acquired from the national parks, notified sanctuaries, or from reserved or protected forests as designated under the Forest Act. In addition, Ms. Sarma indicated that permission for import and export of certain unspecified biological materials may require additional permission of the Director General of Foreign Trade.

¶22. (U) Post did not find any suggestion that visa approvals were linked to NBA approvals. There are no regulations for the shipment of biological resources between states within India. India claims to follow international standards related to permits and handling for the import and export of biological resources, including quarantine procedures. NBA also requires that samples of all imported and exported materials be sent to the designated national repositories (plant, animal, fish, insect, or microbial) for sequencing and future reference.

¶23. (U) Dr. S. K. Sharma underscored that NBPGR, as the national repository for plant material, had primary responsibility for conducting quarantine checks and documenting all imported or exported plant material including seeds, propagates, and transgenic materials. He said NBPGR also had authority to issue import/export permits and phytosanitary certificates. Other national repositories presumably share similar responsibilities and authorities.

MAT AND PIC - THEORY VS PRACTICE

¶24. (SBU) According to the NBA, all agreements for IPR and for commercial transfer of material or knowledge, whether from foreign or Indian parties, must include a section on MAT. The NBA website claims that Indian sponsors are to negotiate MAT with the local organizations before beginning research, but our review of research agreements on NBA's website show they do not generally include MAT. As noted in

paragraph 14, there is a disparity between the theory and practice of MAT negotiation and although BMCs are supposed to play a key role, this is not currently a widespread practice.

¶25. (SBU) Our contacts indicated that government-approved MOUs generally include provisions for IPR and MAT, or are accompanied by Material Transfer Agreements that define those issues. Dr. Arivudai Nambi indicated that in instances where a foreign party is collecting biological resources for a commercial purpose and thus seeking to profit, the NBA can renegotiate MAT after the specimen has been collected - a major disincentive for companies to get involved in specimen collection in India as the renegotiation could eliminate any gain from the research.

¶26. (SBU) The NBA does not require upfront payments but instead imposes a royalty percentage usually running between 2 and 5 percent which goes to the NBA-run biodiversity fund. The National Biodiversity Fund is supposed to disburse funds to state and local groups, presumably through the SBBs and BMCs, although there have been no indications of such transfers taking place. The two NBA committee members we talked with said the royalty policy was still being formulated, the percentages were currently decided on a case-by-case basis, and that the NBA had not yet decided out how it would standardize decisions on royalties. This lack of transparency has led to great consternation in the scientific community.

¶27. (SBU) CSIR's IPR office has 205 approved applications, but has yet to sign an agreement because the NBA is demanding an exorbitant royalty percentage. Our contact would not confirm the percentage demanded, though he did mention 10

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percent at one point in the conversation. Our contact also noted that patents are often licensed to third parties, and that he had asked the NBA for clarification on whether the licensor or licensee would be responsible for paying royalties to the NBA.

¶28. (U) Another major unresolved issue for the NBA is developing guidelines to deal with materials transferred prior to the existence of the CBD, BDA, and NBA. While this applies primarily to UK researchers who collected significant numbers of samples during their stewardship of India, it may also apply to materials shared with the U.S. either independently or through institutes in the U.K. and other countries.

¶29. (SBU) Patent applications in India are required to specify the source and origin of biological materials, and NBA approval is required before a patent can be granted. However CSIR's Mr. Gupta indicated that at the moment, only the Mumbai patent office was verifying NBA approval prior to issuing a patent. Mr. Gupta also said the rules regarding the timing for filing both patent and NBA applications was unclear, and so CSIR was erring on the side of filing first for patent protection and immediately thereafter filing for NBA approval. His logic was that filing first for the patent provides some protection of the information since the NBA application is publicly available.

¶30. (U) In regard to IPR-related applications, the NBA is supposed to conduct a review of traditional knowledge before providing approval. People's Biodiversity Registers are intended to be one mechanism for review of traditional knowledge. In fact, our contacts told us that patent offices in Indonesia, the EU, and other unspecified countries were recently granted restricted access to the PBR databases for that purpose. A second mechanism is the "Wealth of India" compendium which catalogues colloquial and technical information on India's natural resources. It is not clear whether these sources, or any others, are routinely consulted by the NBA.

¶31. (U) There is also conflicting information about negotiation of PIC. Despite claims that PIC is supposed to be negotiated with the local organizations by the Indian sponsor, our Delhi-based contacts suggested that the NBA retains control. Regardless of whether or how the negotiations take place, additional NBA approvals and fees are required any time Indian biological resource materials or information are to be transferred to a party not explicitly named in an original NBA-approved agreement.

COMMENTS

¶32. (SBU) Despite nearly a month of requests A. K. Goyal, MoEF Joint Secretary and India's designated point of contact for the Convention on Biological Diversity, refused to meet with us and claimed various excuses from involvement in Parliamentary sessions to being too busy. This unwillingness to engage is unprecedented and we suspect stems from a desire to avoid discussing a process MoEF knows is severely flawed. Our other contacts, including those at the NBA, were happy to discuss the issues and provide copies of related documentation. They were, however, hesitant to give us definite answers and conceded uncertainty about many of the processes and requirements as they are constantly changing. Indian sponsors are intended to provide guidance to foreign parties, though in many cases they appear not to be aware of the various requirements and processes. The bottom line is that there is no one-stop-shop for a researcher interested in accessing biological resources in India.

¶33. (SBU) The BDA and NBA, in theory and especially in

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practice, appear to be more focused on IPR and financial considerations than on conservation or biodiversity. Though the NBA allegedly has responsibility for ensuring compliance with the BDA and Rules, our contacts were unable to provide any information on specific penalties or enforcement authorities for violations of research, IPR, transfer, or royalty payments. In addition, India has not even begun to address the management and sharing of genetic sequences or the structures of compounds derived from biological resources - both of which could be used to recreate Indian biological resources or their derivatives outside of India.

¶34. (U) Post's contact for further inquiries is EST Officer Heather Broman (email: bromanhw@state.gov).
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